

REGIONAL COORDINATING CENTER MANAGERS BREAKOUT SESSION OCTOBER 16TH, 2018 MONTREAL, CANADA

Todays Presentations:

▶ Time and Effort Reporting for the RCC Manager

Preethy Flet (Medstar) Kinga Aitken (Utah)

► Study Recruitment:

Heena Olalde (lowa)

Cheryl Grant (MUSC)

Kinga Aitken(UTAH)

Site Selection and RCC Growth:

Devin Qualls (Mass Gen)

Stephanie Wilbrand (Wisconsin)

David Haney (CWRU)

Role and Responsibilities of RCC Managers

PREETHY FEIT- MEDSTAR HEALTH KINGA AITKEN- U OF UTAH



Roles of RCC Managers

• Liaison between NCC, cIRB, Trial PM and DM

AND

Satellite sites



Responsibilities

- Leadership
- Ocommunication & Partnership
- Training
- Administrative support for protocol initiation and conduction
- Oversight (protocol adherence, regulatory, screening logs)
- Mentorship

What we can't offer:

 Screening, enrollment, trial conduction at satellite level

Important Tips and Tricks

- Know satellite personnel
- Personal relationships with satellite personnel
- Know where EVERYTHING stands at the sites
 - Regular F.U (in person, phone, email)
 - o webDCU oversight
 - Regular communication about RCC progress
- Be available
- Be creative and helpful
 - Create and share personalized tools for study conduction
 - Foster communication between clinical performing sites for a particular trial

Peter Hannon, MD AtRial Cardiopathy and Antithrombotic Drugs In prevention After cryptogenic stroke (ARCADIA) IRB: 106386 3/30/2018

For questions call Kinga Aitken MPH CCRP, Research Associate at 801-581-5523 (Desk) or 801-577-6073 (Cell)

ARCADIA STUDY DOSING NURSE CHECK OFF

By signing this document, I certify that I have verified the strength and regimen of the study drug in EPIC, it matches the medication package, and the correct dose has been administered.

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	COLORED label		
	(apixaban or placebo)		
	PM: 1 tab from Bottle 2,		
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RCC Management Styles

Several types of Management Styles amongst RCCs including:

- RCC Manager of StrokeNet, and other networks
- RCC Manager of StrokeNet and primary clinical coordinator of StrokeNet trials
- RCC manager of StrokeNet and other grants
- Working within one institution or other institutions

Discussion: How to balance time between different competing priorities

Motivation

- Recognition of hard work
- Tokens of appreciation
- Other motivation methods?



Questions



Thank you!



Study Recruitment

- Kinga Aitken Univ. of Utah
- Cheryl Grant Medical Univ. of South Carolina
- Heena Olalde Univ. of Iowa Hospitals and Clinics





- Daily screening
- Live screenings of BA pages
- Outpatient clinic screening
- Other creative, study specific recruitment methods





@2013 MapQuest Portions @2013 NAVTEQ

Common Challenges in Trial Conduction

Distance

- Consent
- Follow-up







Challenges Overcome

- Ability to conduct remote consenting
- Ability to conduct remote F.U. visits
- Ability to conduct home visits
- Team work and cross coverage







Recruitment at MUSC

- Daily screening in the hospital EDs and admitted stroke patients on stroke floor units
- Residents, floor nurses and clinic stroke staff are educated on available studies and entry requirements
- SPOK Mobile Paging System



- EPIC EMR- Master Stroke List
- Pocket cards and badge buddies, posted trial flowcharts, and staff meeting inservices
- Engaged PIs and Sub-Investigators



Recruitment at MUSC-Other Avenues

- MUSC MyChart patient portal
- Patients grant Research Permissions to MUSC to be contacted about research opportunities.
- Once IRB approval has been received, this method allows the PI/research team to design recruitment reports based on their study criteria and be notified through Epic of patients who meet criteria and have agreed to be contacted.
- Stroke education in the hospital
- SCResearch.org, Researchmatch.org, and Hollings Cancer Center Trials.
- The Registry for Stroke Recovery (RESTORE) and the Health Sciences South Carolina (HSSC) clinical data warehouse



Recruitment at MUSC – Recovery Studies

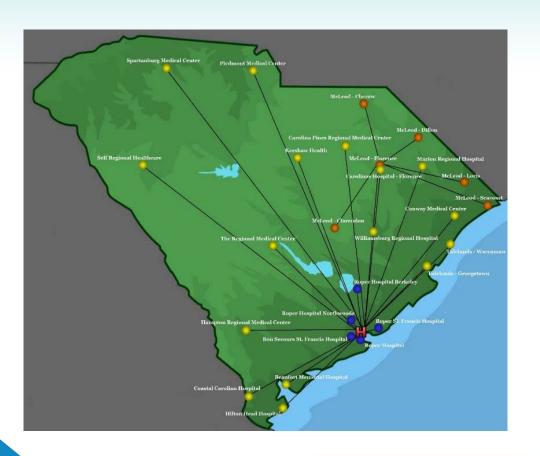
- The MUSC Stroke Recovery Research Center also currently uses various forms of social media in which subjects may learn about research opportunities through word of mouth
 - support group meetings
 - Clinicians
 - health care providers
 - participants
- IRB approved marketing and advertising efforts.
 - social media (i.e. Facebook, Craigslist, Pennysaver Classifieds),
 - YAMMER (MUSC's enterprise social network)
 - newspapers, billboards, flyers, brochures
 - Charleston Area Regional Transportation Authority (city bus system).



Telehealth Recruitment at MUSC

- > Doxy.me -for real-time audio-video communication between the providers and the patients at home or any location suitable for them.
- Electronic consent process may take place on site or remotely
- ➤ Ideally suited for conducting StrokeNet studies at telestroke sites. Features of elC include:
 - eConsent reduces the risk of informed consent noncompliance by providing better management and documentation of the consent process
 - When properly implemented the eConsent document cannot be completed until required fields are completed
 - Provides audit trail
 - Improves record retention (reduces the number of lost consents and HIPAA authorizations)

MUSC Telestroke Network



28 Partner Hospitals

- > 4,702 Hospital Beds
- > 925,000 Annual ER Visits
- 14 Certified Primary Stroke **Care Centers**
- 4 hospitals applying for **Acute Stroke Ready**
 - Smallest 25 beds
 - Largest 540 beds





RECRUITMENT



- Screen inpatient/outpatient stroke service daily
- Alert clinical team of potential candidate for trial
- Team approach to recruitment
- If acute stroke trial, make sure clinical teams from other departments (ER, transfer center, etc) aware also to help with identification
- Make sure clinical teams (including nursing) involved in patients care aware of study.
- Review notes in EMR regarding trials

The Iowa Experience



- DEFUSE 3 Utilize Air Care I and II to help with recruitment
- CREST 2/H Multidisciplinary
 - o PI = Vascular Surgery
 - Investigators from Vascular Surgery, Neurology, Neurosurgery, Radiology, and Cardiology
 - o Coordinators in multiple departments
- ARCADIA
 - TOAST classification in EMR
 - o Team approach to recruitment
 - Kudos e-mails





RCC Manager Role

Site Coordinator for the trial

- o Experience with trials
- Use the knowledge you gain to help your satellite sites participating in the trial

Not site coordinator

- Attend study calls and/or Investigator Meeting if possible
- Know protocols to help your sites
- Make sure to follow up with satellite coordinators



SUBJECT RETENTION

-No one size fits all for the best--Population-specific situation--Flexible scheduling--Multiple contact numbers --Creative motivations-



Also:

- Understanding your audience and the challenges you face personally
- Understand visit schedule required by protocols.
- Proactive approach to subject retention
 - scheduling follow-up visits convenient to patient's schedule but within protocol parameters
 - visit reminder calls
 - development of standard operating procedures for transportation,
 - a stroke support survivor group,
 - · permission from patients for future contact,
 - of equal importance ensuring transportation costs are budgeted appropriately to support successful retention during contract negotiation phases
 - follow-up through telemedicine

Conclusion

- Screen daily for trials
- Find ways to overcome recruitment challenges at your sites
- Use various avenues to help with identification and recruitment
- Educate your teams about the trials
- See if your institution may allow telehealth, aerial crew, or remote consenting.
- As RCC manager, be a resource to your sites

Questions?



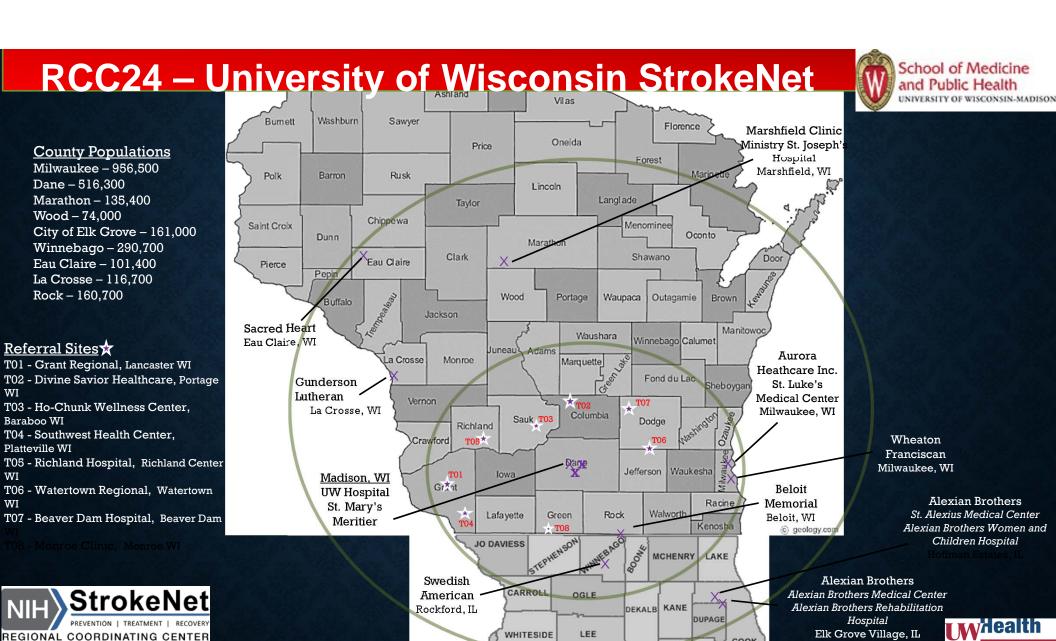
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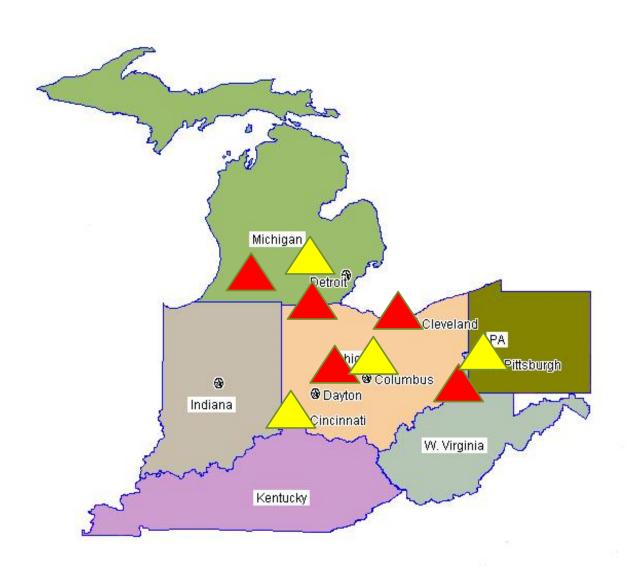


SHARED EXPERIENCES IN RCC SATELLITE GROWTH

RCC Managers:

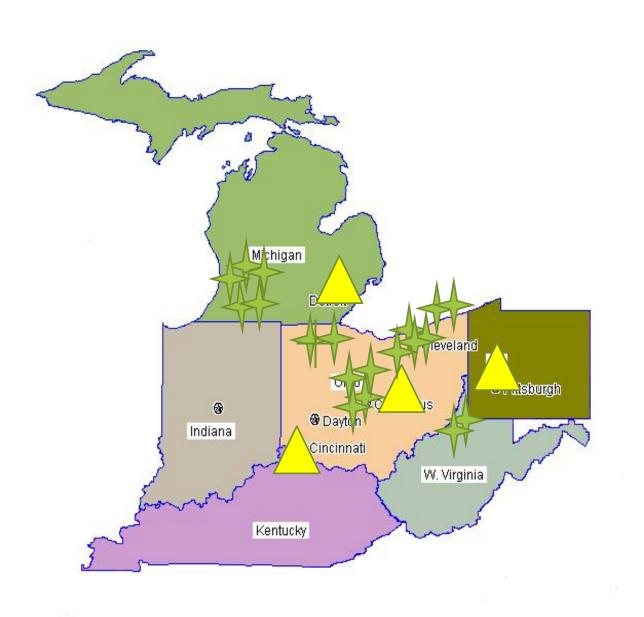
- Devin Qualls (Mass Gen)
- Stephanie Wilbrand (Wisconsin)
 - David Haney (Case Western)





8 Core or Satellite Competing Hospital Systems

Surrounded by 4 RCC

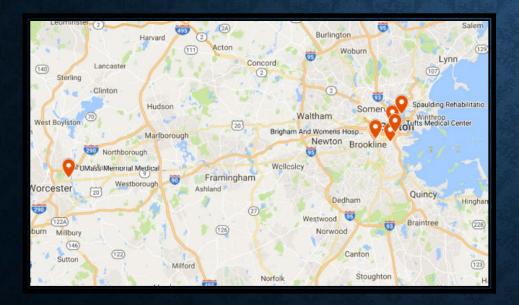


- 8 Core hospitals/ Satellites.
- 43 CPS

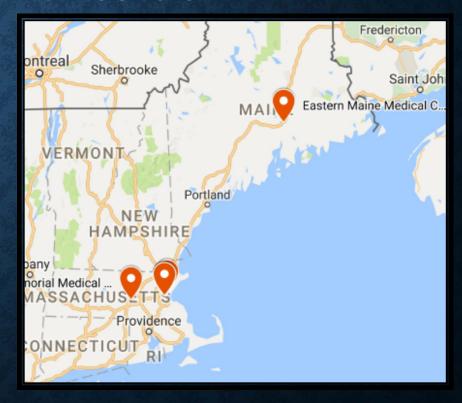


A Member of the NIH StrokeNet Trials Network

NERCC 2013



NERCC 2018



PRO AND CONS OF ADDING / DELETING SITES

- Distance long vs. short
 - Urban / Rural
 - Amount of satellites
 - Satellite structure
- Previous collaboration: clinical trials, telestroke network, etc.
 - Satellites in other states (different laws)
- Working with the same medical record system, imaging, etc.

NERCC SITE SPECIFIC OPERATION QUESTIONNAIRE

- 1. Who will act as Site StrokeNet PI and Coordinator? Please include their full contact information.
- 2. Do you have a local IRB? If not which IRBs have you utilized in the past?
- 2. Have you or your IRB of record worked with a Central IRB?
- 3. Are licenses, training certificates and CVs kept in a central location? Who is responsible for this?
- 4. How does your site assess feasibility for a specific trial?
 - Recruitment Numbers
 - Budget Review
 - Delegation of Authority

NERCC SITE SPECIFIC OPERATIONS QUESTIONNAIRE

- 5. Does your department have a set of general SOPs in place for study activities?
- 6. Describe your department's interactions with the research pharmacy. Is it 24h? Where is study drug stored for acute studies? What is the process for dispensing drug acutely?
- 7. What is your process for screening (determining eligibility)/recruiting patients (approaching for enrollment)? Is this 24h?
 - Acute/ED (0-12hr):
 - Non-Acute/Inpatient (12-24hr):
 - Outpatient/Rehab (sub-acute, chronic, rehab):
- 8. How do you determine a patient's ability to give consent?

NERCC SITE SPECIFIC OPERATIONS QUESTIONNAIRE

- 9. What general processes are in place to facilitate subject retention?
- 10. Who signs off on AEs? How do you know when a patient has been rehospitalized?
- 12. What other stroke studies are you currently participating in?
- 13. Describe your site's standard imaging protocol

NERCC SITE SPECIFIC OPERATIONS QUESTIONNAIRE

	Available for Research (Y/N)	24/7	Business hours (if not 24/7)	Notes
Residents				
Fellows				
Coordinator				
Research				
Nurse				
Research				
Pharmacy				
PT				
OT				
Speech				
Therapy				
CT				
MRI				
Centrifuge				
-80 Freezer				

NERCC NEW SITE CHECKLIST

Locations to tour

- Walk-through of important areas
- This will differ site to site, can include but not limited to: pharmacy, GCRC or equivalent,
 phlebotomy area, lab processing, exam rooms, research MRI/CT location, etc.
- Walk-through of an acute stroke patient
- Monitoring
 - Access to medical records
 - o Space
- Storage
 - o Document
 - o Specimen
 - o Study drug (local or central)

NERCC NEW SITE CHECKLIST CONT.

Discussion

- Determining feasibility
 - o How is this done, by whom, and using what resources
 - o Use of feasibility data
- cIRB
 - o Logistics of using an outside academic IRB
- Site SOPs

PRO'S:

- Opportunity for a new satellite to participate in StrokeNet.
- Increasing opportunity for study trial recruitment.
- Participation on several trials.
- Increasing collaboration.
- Educational Arm.

CHALLENGES:

- Infrastructure of the new site, (MTA and RA, PTA's).
- Lack of recruitment, slow regulatory process.
- Cost of trials, study site logistics and metrics.
- Communications and RCC managers time. Lack of control.
- Communications and Fairness.

Questions?



Thank you!

